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EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,419

Applicant(s)

VAN GELDER ET AL.

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed November 23, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for, method steps of and instructions for “determining whether adequate ventricular fusion resulted” must be shown or the feature(s) canceled from the claim(s). The Examiner also recommends amending the algorithms depicted in the drawings to exemplify all subsequent method steps listed in lines 8-22 of Claim 1 as a way to overcome this rejection. These steps must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure

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must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification contains some references to commonly owned patent applications without application numbers. The Examiner respectfully requests that this information be updated along with any other referenced applications without application numbers or referenced applications that have since issued.

4. The abstract of the disclosure is objected to because it phrases such as "the present invention", "the invention enables" and "according to the invention" which may be implied.

Correction is required. See MPEP § 608.01(b).

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

6. Claims 1 and 19 are objected to because of the following informalities: it is suggested that Applicant specify the meaning of acronym "LEPARS" before referring to "left ventricular pacing, right ventricular sensing" as "LEPARS in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it is unclear to the Examiner exactly how it is determined that adequate ventricular fusion has or has not resulted.

The Examiner makes reference to page 29, paragraph 81 where it is disclosed that

temporal ECG or EGM tracings of at least the resulting QRS complexes, acutely invasive or chronic LV or RV fluid pressure measurements, monitor signals from an accelerometer coupled to the myocardium, and the like

are exemplary tests for determination of adequate fusion. Applicant has failed to elaborate on such tests and the steps that they would entail. For example, is a pressure measurement compared to a threshold? What about these different tests yields a declaration of a situation

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involving adequate and inadequate fusion? The Examiner is also unsure of how "in the event that an adequate ventricular fusion resulted" a LEPARS interval is measured as defined by Claim 1. According to the specification at page 29, paragraph 81, the measuring of the LEPARS interval is described to occur at the same time as the delivering of the LEPARS-based, pre-excitation pacing therapy and at the same time as any confirmation tests which determine if adequate fusion has occurred.

9. The Examiner is also unsure of how the LEPARS interval is maintained "over a range of different pace heart rates" since the specification fails to provide adequate support for those limitations of Claim 19.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 49 recites the limitation "the other said cardiac cycles" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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14. As written Claims 5, 23 and 41 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims recite parts of the human body per se without referring to any related apparatus features or method steps. To overcome this rejection, the Examiner recommends changing the language of Claim 5 to read as follows:

“5. A method of claim 4, wherein the step of delivering a pre-excitation pulse to said at least one electrode in the left ventricular chamber comprises delivering the pulse to a portion of one of:

a coronary sinus,
a portion of a great vein,
a portion of a vessel branching from the great vein.”

15. The language of Claims 23 and 41 should be modified similarly to overcome the 35 U.S.C 101 rejections against them.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 37-47 and 50-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill (U.S. 6,871,096).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

18. As to Claims 37-40 and 46-47, Hill discloses an apparatus and computer-readable medium that carry out a method of bi-ventricular, fusion-pacing therapy delivery to a non-synchronous pair of ventricles, including delivery of a single ventricular pacing pulse to a relatively late activated ventricular chamber to promote mechanical synchrony between the late activated ventricular chamber and a relatively more rapid, intrinsically conducting ventricular chamber comprising measuring an intrinsic atrio-ventricular AV delay interval for a first-to-depolarize ventricular chamber (V1, right ventricle) for at least one prior cardiac cycle and delivering during a subsequent cardiac cycle at least one ventricular pacing pulse to a second-to-depolarize ventricular chamber (V2, left ventricle). Hill also discloses that the ventricular pre-excitation pacing pulse is delivered at the expiration of a V2 pacing interval, wherein the V2 pacing interval is temporally shorter than the intrinsic atrio-ventricular AV delay interval of the V1 chamber (see Hill column 16, lines 43-67, column 17, lines 1-5 and column 19, lines 24-54). Hill further discloses that the ventricular pacing pulses are pre-excitation pacing pulses (see Hill column 7, lines 1-15).

19. As to Claim 41, Hill discloses that the bipolar, endocardial coronary sinus lead 52 is passed through a vein and the RA chamber of the heart 10, into the coronary sinus and then inferiorly in a branching vessel to extend the proximal and distal LV CS pace/sense tip electrodes 48 and 50 alongside the LV chamber. The distal end of such a CS lead is advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus, the coronary

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sinus, and into a coronary vein descending from the coronary sinus, such as the lateral or posteriolateral vein (see Hill column 10, lines 1-10). Hill also discloses an alternative embodiment the LV CS pace/sense tip electrodes 28 and 30 may reside in a portion of a great vein or a portion of a vessel branching from the great vein (see Hill column 10, lines 18-25).

20. As to Claims 42-45, Hill discloses that the ventricular pre-excitation pacing pulse is delivered between a tip 40 and a ring 38 pacing electrodes (see Hill column 9, lines 50-55) and that the measuring step occurs between at least one of a tip and a ring pacing electrode, a pair of electrodes, an epicardial electrode and a second electrode, a subcutaneous electrode and the second electrode (see Hill column 9, lines 30-67). Hill further discloses that control circuit 350 selects associated sense electrode pairs to be coupled with the sense amplifiers of the system (see Hill column 13, lines 31-50). It is inherent that at least one of the electrodes of the LV CS lead 52 is adapted to couple to an anterior portion of the left ventricle or epicardially to the left ventricle due to Hill, column 10, lines 6-25.

21. As to Claims 50 and 51, Hill discloses an IPG circuit 300, programmed in a rate responsive mode, wherein signals output by one or more physiologic sensors are employed as a rate control parameter via patient activity sensor 322. Hill also discloses that the activity sensor 316 monitors a physiologic cardiac parameter such as QT time intervals, oxygen levels, pressure levels, pH levels and respiration levels during delivery of the fusion-based cardiac pacing regimen (see Hill column 10, lines 66-67 and column 11, lines 1-21).

22. Claims 37-40, 42-43, 46-47 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al. (U.S. 2005/0137630) (herein Ding). As to Claims 37, 39-40 and 46-47, Ding discloses an apparatus and computer-readable medium 10, 12 (see Ding Fig. 1) that carry

out a method of bi-ventricular, fusion-pacing therapy delivery to a non-synchronous pair of ventricles, including delivery of a single ventricular pre-excitation pacing pulse to a relatively late activated ventricular chamber to promote mechanical synchrony between the late activated ventricular chamber and a relatively more rapid, intrinsically conducting ventricular chamber (see Ding page 3, paragraphs 16-18) comprising measuring an intrinsic atrio-ventricular AV delay interval for a first-to-depolarize ventricular chamber (V1, right ventricle) for at least one prior cardiac cycle and delivering during a subsequent cardiac cycle at least one ventricular pre-excitation pacing pulse to a second-to-depolarize ventricular chamber (V2, left ventricle). Ding also discloses that the ventricular pre-excitation pacing pulse is delivered at the expiration of an AV delay interval AVD, read as a V2 pacing interval, wherein the V2 pacing interval is temporally shorter than the measured intrinsic atrio-ventricular AV delay interval of the right ventricular chamber (see Ding Fig. 3 and page 6, paragraph 40).

23. As to Claim 38, Ding discloses that the techniques for setting resynchronization pacing parameters as described may be implemented in a number of embodiments such as where the step of measuring the atrio-ventricular AV delay interval further comprises calculating an average AV delay interval or using a lookup table and procedure (see Ding page 4, paragraph 27).

24. As to Claims 42-43, Ding discloses a left atrial sensing/pacing ring electrode 53a and tip electrode 53b of bipolar lead 53c, and a right atrial sensing/pacing ring electrode 43a and tip electrode 43b of bipolar lead 43c. Ding also discloses a right ventricular sensing/pacing ring electrode 23a and tip electrode 23b of bipolar lead 23c and a left ventricular sensing/pacing ring electrode 33a and tip electrode 33b of bipolar lead 33c. Ding further discloses that in this

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embodiment, the device is equipped with bipolar leads that include two electrodes, which are used for outputting a pacing pulse and/or sensing intrinsic activity. (see Ding page 2, paragraph 13).

25. As to Claim 50, Ding discloses that in order to optimally specify the bi-ventricular pacing parameters for a particular patient, clinical hemodynamic testing may be performed after implantation where the parameters are varied as cardiac function is assessed. In order to accomplish this, Ding further discloses that a patient may be given resynchronization stimulation while varying pre-excitation timing parameters in order to determine the values of the parameters that result in maximum cardiac performance, as determined by measuring a parameter reflective of cardiac function such as maximum left ventricular pressure change (dP/dt), arterial pulse pressure, or measurements of cardiac output (see Ding page 3, paragraph 21).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill in view of Sholder (U.S. 5,741,308). As to Claim 48, Applicant differs from Hill in that the at least one prior cardiac cycle comprise at least three consecutive, immediately prior cardiac cycles. The Examiner considers the use of measuring an intrinsic atrio-ventricular conduction delay interval over several consecutive cardiac cycles and then computing an average intrinsic atrio-ventricular

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conduction delay intervals for use in modifying pacing parameters to be conventional and well known in the art with Sholder being but one example. Sholder teaches that the intrinsic atrio-ventricular conduction delay interval “may be determined or measured over several cardiac cycles, e.g., averaged over several cardiac cycles”, so that pacing intervals derived from such intrinsic atrio-ventricular conduction delay intervals are not set to an erroneous value that is based on a single intrinsic atrio-ventricular conduction delay interval measurement that is not representative of the correct natural conduction time. It is inherent or at least obvious to one having ordinary skill in the art that the phrase “several” includes at least three cardiac cycles (see Sholder column 3, lines 51-67 and column 4, lines 1-33).

28. As to Claim 49, the previously modified Hill reference discloses the claimed invention as discussed above except that it is not specified that the most recent of the at least three consecutive cardiac cycles is mathematically weighted more heavily. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the instructions as taught by Hill in view of Sholder to mathematically weigh the most recent intrinsic atrio-ventricular conduction delay interval higher than previously measured intrinsic atrio-ventricular conduction delay interval since it was known in the art that you want the measurements to be as accurate and close to “real conduction time” as possible and since it is desirable to pace the heart as close to its natural function as possible.

29. Claims 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Mower (U.S.2005/0055058). As to Claim 41, Ding discloses the claimed invention except that the at least one electrode adapted to be coupled to a left ventricular chamber is not

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adapted to be positioned via one of a coronary sinus, a portion of a great vein, or a portion of a vessel branching from the great vein.

Mower, however, discloses a method and apparatus for intrachamber resynchronization that senses cardiac conduction and determines the progress of contraction of the heart. Based on the progress of contraction, the left ventricular chamber of the heart is then stimulated at a plurality of locations for the purpose of improving hemodynamic performance and increasing cardiac output in a patient who is suffering from congestive heart failure. Mower also discloses that in an alternative embodiment a pre-excitation voltage may be applied to pre-condition a portion of the heart for the resynchronization therapy (see Mower Abstract, page 1, paragraphs 12-14 and page 2, paragraph 15). Mower further discloses that the left ventricular pacing electrode 404 is safely advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus (CS), the CS, and into a coronary vein descending from the CS, and is implanted at a desired pacing site in the coronary vein (see Mower page 5, paragraphs 60-61). Therefore it would have been obvious to one having ordinary skill in the art that the time the invention was made to modify Ding in view of Mower to include an electrode adapted to be coupled to a left ventricular chamber via the coronary sinus in order to provide a safe system for increased hemodynamic efficiency of a heart experiencing a conduction deficiency and to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

30. As to Claim 45, Ding discloses the claimed invention except that the at least one electrode for delivering pre-excitation pulses is not adapted to couple epicardially to the left ventricular chamber.

Mower, however, discloses a method and apparatus for intrachamber resynchronization that senses cardiac conduction and determines the progress of contraction of the heart. Based on the progress of contraction, the left ventricular chamber of the heart is then stimulated at a plurality of locations for the purpose of improving hemodynamic performance and increasing cardiac output in a patient who is suffering from congestive heart failure. Mower also discloses that in an alternative embodiment a pre-excitation voltage may be applied to pre-condition a portion of the heart for the resynchronization therapy (see Mower Abstract, page 1, paragraphs 12-14 and page 2, paragraph 15). The ventricular electrodes used for pacing the left ventricle can alternatively be placed in other locations besides the coronary sinus or the coronary vein, such as in the epicardial wall of the left ventricle (see Mower page 5, paragraph 62). Therefore it would have been obvious to one having ordinary skill in the art that the time the invention was made to modify Ding in view of Mower to include an electrode adapted to be coupled the epicardial wall of the left ventricular chamber to provide a safe system for increased hemodynamic efficiency of a heart experiencing a conduction deficiency and to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

31. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Alt et al. (U.S. 6,370,427) (herein Alt). Ding discloses the claimed invention as discussed above except that the at least one ventricular pre-excitation pacing pulse is not specified to be delivered between a a coil and a can-based electrode, a pair of coil electrodes, an epicardial electrode and a second electrode, or a subcutaneous electrode and the second electrode.

Alt, however, discloses a device and method for dual chamber bi-ventricular pacing and defibrillation comprising a left pacing lead 72 including coil electrode 77, a tip electrode 73 located on a single lead in the anterior portion of the left ventricle (see Alt. Fig. 4) for improved hemodynamic performance in patients with heart failure (see Alt column 3, lines 13-15). Alt further teaches that a can-based electrode may be used which results in a lower excitation to the apex of the left ventricle (see Alt column 3, lines 1-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ding in view of Alt to include an anterior left ventricular electrode configuration comprising a tip and a pair of electrodes or a coil and a can-based electrode to allow the pair of electrodes to be on a single lead to improve the invention's ability to improve hemodynamic performance or to employ a lower excitatory stimulus to the apex of the left ventricle while simultaneously stimulating the right.

32. Claims 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Sholder. As to Claim 48, Applicant differs from Ding in that the at least one prior cardiac cycle comprise at least three consecutive, immediately prior cardiac cycles. The Examiner considers the use of measuring an intrinsic atrio-ventricular conduction delay interval over several consecutive cardiac cycles and then computing an average intrinsic atrio-ventricular conduction delay intervals for use in modifying pacing parameters to be conventional and well known in the art with Sholder being but one example. Sholder teaches that the intrinsic atrio-ventricular conduction delay interval "may be determined or measured over several cardiac cycles, e.g., averaged over several cardiac cycles", so that pacing intervals derived from such intrinsic atrio-ventricular conduction delay intervals are not set to an erroneous value that is

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based on a single intrinsic atrio-ventricular conduction delay interval measurement that is not representative of the correct natural conduction time. It is inherent or at least obvious to one having ordinary skill in the art that the phrase “several” includes at least three cardiac cycles (see Sholder column 3, lines 51-67 and column 4, lines 1-33).

33. As to Claim 49, the previously modified Ding reference discloses the claimed invention as discussed above except that it is not specified that the most recent of the at least three consecutive cardiac cycles is mathematically weighted more heavily. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the instructions as taught by Ding in view of Sholder to mathematically weigh the most recent intrinsic atrio-ventricular conduction delay interval higher than previously measured intrinsic atrio-ventricular conduction delay interval since it was known in the art that you want the measurements to be as accurate and close to “real conduction time” as possible and since it is desirable to pace the heart as close to its natural function as possible.

Double Patenting

34. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

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claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

35. Claims 37-47 and 50-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-27 of U.S. Patent No. 6,871,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

36. Claims 48-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-27 of U.S. Patent No. 6,871,096 in view of Sholder. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the

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patented claims or an obvious variant thereof. Applicant differs from the claims of Hill in that the at least one prior cardiac cycle comprise at least three consecutive, immediately prior cardiac cycles. The Examiner considers the use of measuring an intrinsic atrio-ventricular conduction delay interval over several consecutive cardiac cycles and then computing an average intrinsic atrio-ventricular conduction delay intervals for use in modifying pacing parameters to be conventional and well known in the art with Sholder being but one example, as discussed above.

37. Claims 37-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 of copending Application No. 10/803,570 (Amended August 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

VanHout (U.S. 2003/0014084) discloses a method and apparatus for monitoring conduction times in a bi-chamber pacing system in a rate-responsive pacemaker.


Auricchio et al. (U.S. 5,935,160) discloses a left ventricular access lead for heart failure pacing adapted to be placed in the coronary vein and employed for bi-ventricular pacing.


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39. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jessica L. Reidel
Examiner
Art Unit 3766
10/05/06


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766